REMARKS/ARGUMENTS

Claims 2-21 and 23 remain under consideration in this application. Claim 22 has been cancelled.

With respect to the examiner's objection to claims 21, 22, and 4, Claim 22 has been cancelled, making the objection to claims 21 and 22 moot. Applicant respectfully submits that claim 4 further limits claim 23 by requiring that the material naturally adhere to the interior of the user's mouth. Claim 23 does not require that the disk adhere naturally. As such, claim 4 further limits claim 23 and removal of the objection is requested.

The examiner has withdrawn the allowance of currently pending claims 2-16 and 23 in view of newly discovered references(s) to Anderson (5,893,365) and Vigilia (4,881,540). Yet, previously allowed claims 12 and 6-9 are rejected solely over the previously cited reference to Neidhart et al. (3,658,058). Applicant respectfully submits that neither new references Anderson and Vigilia, nor previously cited Neidhart, render the claimed invention obvious.

The claimed invention is directed to a mouthpiece for preventing air leakage when used in association with continuous positive airflow pressure (CPAP). During nasal CPAP (nCPAP), a machine supplies a steady stream of air through a tube that connects to a plastic mask covering the user's nose. The air entering the nose provides sufficient air pressure to prevent the tissues in the user's airway from collapsing during sleep. If air escapes through the mouth, the effective pressure on the tissues in the airway lessens, thereby decreasing the effect of the nCPAP. The mouthpiece of the present invention is designed to prevent air from leaking out of the user's mouth during nCPAP treatment.

The mouthpiece comprises a thin flexible disk that is inserted between a user's teeth and lips. In one claimed embodiment, the disk adheres to the interior of the user's lips, cheeks or combination thereof to seal the user's mouth. Because the disk is thin and flexible, it is comfortable for the user to wear during sleep, which is when nCPAP is administered. In one

claimed embodiment, the mouthpiece comprises a bite block specifically designed to position the user's teeth in a manner to maintain an open airway. In addition, the bite block is designed such that in can position the user's teeth while allowing the disk of the mouthpiece to maintain a seal with the lips and/or cheeks. In another claimed embodiment, the device contains a one-way safety valve. Unlike safety valves used in devices designed to prevent snoring that prevent air from entering through the mouth, the safety valve of the present invention allows air to enter mouth in the even the nCPAP device stops working.

With respect to the Examiner's rejection of claim 12 over Neidhart, Neidhart is directed to a device for supporting a breathing tube in the mouth. The breathing tube is inserted in the user's mouth so that the user can breathe freely. The supporting device of Neidhart supports clips for the user's nose, to prevent breathing through the nose, thus forcing breathing through the mouth. Thus, the device of Neidhart performs the opposite function of the mouthpiece of the present invention, which does not interfere with nose breathing and prevents air from escaping through the mouth. There would be no suggestion to apply the teachings of Neidhart to a device used in association with nCPAP, wherein an open nasal passage is essential.

The examiner asserts that Neidhart discloses a flexible disk (4). In fact, element 4 of Neidhart is a flange surrounding a breathing tube. There simply is no disk disclosed in Neidhart. Furthermore, there is no suggestion to employ a disk, insofar as a disk would be incompatible with the breathing tube.

Furthermore, Neidhart does not disclose a bite block as claimed. Neidhart discloses a bite plug, which functions as a piece to be gripped between the teeth to hold the breathing tube in place. In contrast, the configuration and width of the claimed bite block are important to the function of the bite block, which is to position the user's jaw slightly forward from a natural resting position to maintain an open airway. The claimed bite block comprises an arm extending perpendicular to the disk and a flange extending perpendicular to the arm, wherein the width of the flange and arm are substantially equal to 15 mm. The configuration and width of the bite

block are not an obvious matter of design choice, but rather are employed for the particular purpose and solve the particular problem of maintaining an open airway during nCPAP. Nothing in Neidhart discloses or suggests that the bite pieces disclosed therein have such a configuration or perform such a function. Furthermore, nothing in the secondary Anderson, Vigilia or Moulton references teaches or discloses the bite block of claim 12. As a result, claim 12 is not obvious over Neidhart et al. alone, or in combination with Anderson, Vigilia and/or Moulton.

Claims 13-15 depend from independent claim 12. As discussed above, independent claim 12 is patentable over Neidhart et al. alone and in combination with Anderson, Vigilia and/or Moulton. As a result, dependent claims 13-15, which contain all of the limitations of independent claim 12, are also patentable over Neidhart in view of Anderson, Vigilia and/or Moulton.

The Examiner has rejected claim 16 over Moulton, in view of Vigilia. The examiner asserts that it would have been obvious to modify the device of Moulton to employ material that adheres to the interior of the user's lips and cheeks as disclosed in Vigilia. Applicant respectfully disagrees. Moulton is directed to plate designed to be placed between the lips and held in contact with the teeth of the user to prevent snoring. Nothing in Moulton discloses or suggests that the plate be adapted to adhere to the interior of the user's lips or cheeks, or that such adhesion or the seal created thereby would be desirable. Rather, Moulton teaches away from such a configuration by indicating that the plate should be held in contact with the teeth and gums.

In contrast, Vigilia is directed to a device for assisting in artificial respiration. The device comprises a conduit defining an airway with an outwardly projecting flange portion to be received in the user's mouth and seal against the inside surface of the lips. Such a seal is required for efficient transmission of respiring air (col. 1, lines 49-50). There is nothing in Vigilia or Moulton to suggest that such a seal is necessary or desirable in the device of Moulton, which is used for a totally different purpose. Such a modification is not a mere matter of design choice, in that it serves a particular purpose and solves a stated problem when used in nCPAP,

namely to prevent air leakage that would lessen the effective air pressure in the user's airway. As a result, the device of claim 16 is not obvious over Moulton in view of Vigilia.

The examiner has rejected claim 23 over Neidhart/Anderson as applied to claims 12 and 13, in further view of Vigilia. As discussed above, Neidhart in no way discloses a disk. Nor does Vigilia. Rather, Neidhart and Vigilia are both directed to a breathing tube surrounded by a flange. Anderson does disclose a sheet, but, similar to Moulton, the sheet of Anderson is in primary contact with the user's teeth, not the lips (col. 5, lines 50-52). Also as in Moulton, there is no suggestion that the sheet adhere to the interior of the user's lips. And, as discussed above, there is no suggestion in Vigilia or Anderson that the seal of Vigilia be used in the device of Anderson or that such a seal would be desirable. As a result, claim 23, and claims 2-11 which depend therefrom, are not obvious over Neidhart, Anderson and/or Vigilia.

The examiner rejected claim 17, 19 and 20 over Pantino in view of Vent and Saliva Shield. Applicant respectfully submits that the Examiner has not established that the Vent and Saliva Shield reference is prior art. The IDS submitted with the application indicates the publication date for the Vent and Saliva Shield brochure was unknown, but was at least as early as 2001. Applicant submits herewith an affidavit indicating that applicant obtained the brochure at a trade show in June of 2001, which is within one year of applicant's filing date. Applicant has no knowledge, and the Examiner has not established, that the brochure was available prior to that date. As such, there is no evidence the brochure is prior art under section 102(b). As a result, the Vent and Saliva Shield brochure is not prior art against the present application, and removal of the rejection of claims 17, 19 and 20, as well as claims 18 and 21, which depend from claim 17, is respectfully requested.

In view of the foregoing amendments and remarks, it is respectfully submitted that the claims are now in condition for allowance and eventual issuance. Such action is respectfully requested. Should the Examiner have any further questions or comments which need be

addressed in order to obtain allowance, he is invited to contact the undersigned attorney at the number listed below.

Acknowledgment of receipt is respectfully requested.

Respectfully submitted,

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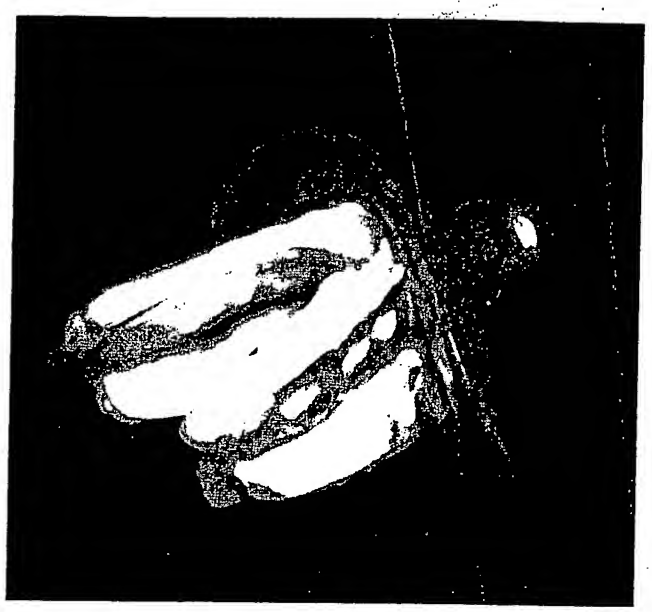
Exhibit A

Vent and Saliva Shield™



A Vent and Saliva Shield is available for the TAP appliance. It is an EVA device that covers the adjustment knob and is then placed under the lips. It allows the patient to swallow easily and prevents mouth breathing and drying of the mucous membranes in the mouth while wearing the TAP®.

Most patients who have tried the shield have felt that it is a great addition to the appliance. If the Vent and Saliva Shield seems to be too large or uncomfortable, it can be put in hot water, formed to the patient's mouth and be trimmed to size.

The Vent and Saliva Shield:

- is made from a soft easily remoldable material
- prevents mouth-breathing and drying of mucous membranes in the mouth
- prevents venting if CPAP is worn in conjunction with TAP®.

Materials Used:

- 1 mm Ethyl Vinyl Acetate Polymer

■ Airway
■ ■ Management
■ ■ ■ Incorporated
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